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(54) Title: USE OF SENSOR AND SYSTEM FOR MONITORING HEART MOVEMENTS

(57) Abstract: System for monitoring heart status. The system includes at least one sensor (2) arranged to be fastened in mycoardium and to produce signals as a function of movement, an amplifier and a calculating unit being arranged to amplify and calculate the signals, to determine the frequency distribution of the signals, a comparator to compare the frequency distribution with a pre-set standard distribution, and an alarm transmitter designed to give a signal when the difference between said distributions exceeds a certain value.

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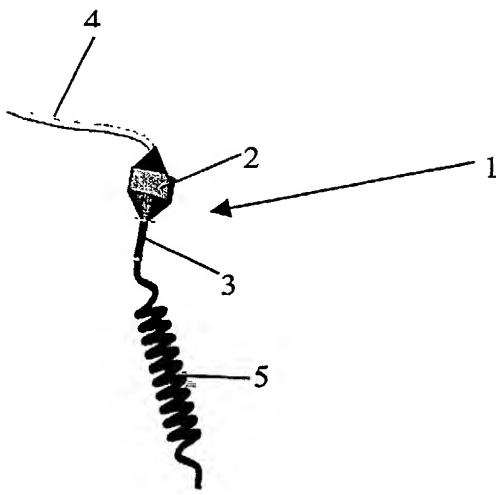
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USE OF SENSOR AND SYSTEM FOR MONITORING HEART MOVEMENTS.

When the blood supply in a cardiac vessel is obstructed (e.g. by ischemia, i.e. when the

5   heart muscle does not receive sufficient oxygen) the muscles supplied by this artery will

initiate an anaerobic metabolism and gradually lose contractility, which in turn results in

a reduced heart activity (pumping effect). Often, surgical intervention is required in

patient whose supply of blood is thus obstructed. The state of the patient's heart can be

measured and monitored in several ways before, during and after an operation. The

10   most common measurement of ischemic heart disease and reduced heart activity is

ECG, systolic blood pressure (low sensitivity), central venous oxygen saturation

through a Swan Ganz catheter (high sensitivity) and measurements of the heart activity

through a Swan Ganz catheter.

15   Following heart surgery, for instance for angina pectoris, where a graft – a new vein –

is laid past the occluded point in the coronary artery (a "bypass operation"), it is of vital

importance that the activity be monitored during the first few days following surgery.

During the initial phase after the operation, occlusion of a graft surgically inserted into a

small cardiac vessel is a risk to the patient. Such an occlusion does not necessarily

20   present any immediate haemodynamic signs. A direct measurement of the movements

in the muscle supplied by the target artery may however provide a higher sensitivity and

earlier information regarding dysfunction.

A sensor system that can easily measure the movements of the heart muscles following

25   heart surgery, particularly after revascularisation of the heart, would be an excellent

monitoring tool for early warning and indication for re-intervention.

There are several types of measuring devices that may be used to measure the

movement of the heart muscle. One method used to evaluate the heart movement is ultra

30   sound imaging. However, this is relatively unsuitable due to the fact that such

monitoring would require manual guiding of the ultra sound transducer. CT and MR

are not suitable for post-operative monitoring a patient over a period of time, among other things because the use of such equipment would be very expensive.

It has now been found that an efficient way of monitoring the state of a patient's heart after an operation is to use a light sensor system that may be fitted to the surface or immediately below the outer surface of the heart muscle, and which emits signals that reflect the movements of the heart. This may be one or possibly more sensors arranged in a pattern in order to monitor a heart surface, and may be one of the following types:

1. Inertia-based elements such as accelerometers and gyroscopes based on:
       Capacitive sensor
       Piezo-resistive sensor
       Piezoelectric sensor
2. Resonating accelerometers
3. Thermal accelerometers
4. Electro-mechanical sensors (position sensors, gyroscopes, potentiometers).
5. Magnetic sensor elements
6. Acoustic sensor elements
7. Optical sensor elements.
8. Bio-sensors (to register e.g. pCO_2 instead of movement)
9. Combinations of the above. As an example, bio-sensors may be integrated into an electrode together with an accelerometer.

Moreover, it is known to equip a pacemaker electrode with an accelerometer for permanent implantation into the heart in order to detect irregularities in the heart rhythm, and which starts the pacemaker when such irregularities occur, cf. US patents no. 4 428 378, no. 4 140 132 and no. 5 833 713. Such a pacemaker device however, is not suited for such use as mentioned above, as this is placed in the apex inside the right or left ventricle . Prior art detects arrhythmia but will not be able to measure changes in the contractility of the heart muscle in specific areas as a function of the blood supply. Thus one of the objects of the invention is to make a sensor element small enough to allow it to be placed underneath the membrane in the heart surface (epicardium) of a

patient in the same manner as temporary pacemaker electrodes that today are routinely implanted during any bypass operations on the heart. A pattern of sensors will make it possible to monitor the surface movements of the heart during the convalescence period, after which it can be withdrawn without requiring surgical intervention. Optionally, the

5   sensor may be integrated into the pacemaker electrode, to allow the same electrode to be used both for measuring movements and pacing the heart when required.

The sensor is placed on the surface in the area that is supplied by the vessel that has been revascularised, e.g. apex in the case of revascularisation of the LAD (Left anterior

10   descending), as the risk of compaction is at its greatest in the vessels which have undergone surgery. Preferably, the sensor is fastened by being placed between the epicardium and the myocardium in the same way as that used today to fasten temporary pacemaker electrodes..

15   A preferred concept is based on a capacitive accelerometer that can measure low frequencies down to 0 Hz and with large amplitudes. However, this is larger and heavier than the piezoelectric and piezo-resistive units, but is based on transport of very low energy. This will be crucial in said application. Placing the electronics in the sensor in order to prevent noise from stray capacitance in the wires from affecting the signal to

20   any significant degree, and using micro/nano electromechanical methods (MEMS/NEMS) of reduction, e.g. by laying thin structures on top of a silicone substrate (surface micro machining), will allow these to compete with the above both in terms of size and characteristics.

25   Another preferred concept is based on the use of a piezoelectric accelerometer. Such accelerometers can be very small and light if based on thin films of piezoelectric material laid on a supporting structure. Such a sensor will also manage with only two conductors (wires), which is an advantage.

30   Another preferred concept is based on a piezo-resistive accelerometer, which can also be based on surface micromachining of e.g. a silicone substrate. As the piezo-resistive principle is not as sensitive to surrounding electrical noise, such as that induced via the

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wires to and from the sensors, this will allow the construction of a very small sensor with the electronics placed externally.

5   A method based on Bulk Micromachining will, with reduction (miniaturisation), also be a good alternative for this.

Thermal accelerometers based on convection have a good combination of sensitivity and overload protection.

10   Resonating sensors, both accelerometers and gyro sensors, are relatively complex, and in the case of gyro sensors, they are based on Coriolis acceleration. These are high precision sensors.

The above is provided with a device of the type mentioned by way of introduction, the
15   characteristics of which appear from the independent claims. Further characteristics of the invention appear from the remaining, dependent claims.

In the following, the invention will be described in greater detail with reference to the drawing, in which:

20   Fig. 1a   shows a detail of a commercially available temporary
                             pacemaker electrode fitted with a sensor such as a triaxial
                             accelerometer;

                Fig. 1b   shows the entire pacemaker electrode of Fig. 1a;

                Figs. 2a -b shows the acceleration before and after occlusion;

25   Fig. 3   shows a spectrogram of the acceleration signal throughout
                             the course of events during artificially induced occlusion and
                             ischemia;

                Figs. 4a-4c shows the frequency distribution calculated by means of a
                             fast Fourier transform;

30   Fig. 5   is a curve showing the energy (X_i) over time for a specific
                             frequency on Fig. 3;

                Figs. 6-12   illustrate the signal processing in example 2 below;

Figs. 13 - 14 illustrate the placement of the sensor on an active heart;

Figs. 15 - 16 illustrate the connection of the sensor to a larger system.

Fig. 1 illustrates a preferred embodiment of the invention with a commonly known

5   temporary pacemaker electrode for use in the present invention. Reference number 2

denotes the accelerometer sensor arranged immediately above the conductive

pacemaker electrode 3. It is envisaged that this 1-3-axis sensor 2 in particular be

developed with micro-electro-mechanical or possibly nano-electro-mechanical methods

(MEMS/NEMS) in order to make it small enough for such special purposes. Reference

10   number 4 denotes insulated conductors to the pacemaker for connecting this to a

pacemaker machine externally of the patient, and the wire 5 is the connecting wire. At

the end of wire 5 is a hook shaped needle 6 for placing the pacemaker in myocardium,

and the end of the wire 4 is provided with a straight needle to allow the wire to be

passed through the patient's thorax to the pacemaker machine. The accelerometer

15   sensor 2 furthermore has a shape, indicated in Fig. 1, which gives good contact with the

heart muscle and at the same time allows it to be withdrawn from the heart muscle

without damaging tissue etc. The wire 5 has been given the form of a spring, and upon

insertion, this is tightened to provide good contact between the accelerometer sensor 2

and the heart muscle. Following insertion, the hook shaped needle 6 is cut, so that upon

20   subsequent removal, the wire can be pulled out of the thorax area together with the

accelerometer sensor.

However, the construction of the sensor is not dependent on the senor also being

equipped with a temporary pacemaker sensor. Other similar constructions of the sensor

25   are also possible. On the whole, such a construction will generally be the same as that

used for different temporary pacemaker electrodes.

A sensor for use in the present invention must meet the following requirements:

30   1. Small; meaning a size similar to that of the conducting nipple of a temporary

pacemaker electrode.

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2. Light so as not to interfere with the proper motion of the heart (small pressure forces).

3. Sensitive to low frequencies, e.g. frequencies in the area 0<f<200 Hz, i.e. a frequency range that registers the various frequency components of which the heart movement consists.

4. Sensitive to amplitudes in the voltage range 0<V<2.5V, with a sensitivity of more than 600mV/g

5. Low energy exchange in the sensor element. This is essential to ensure that the sensor element does not emit electrical pulses to interfere with the functioning of a heart.

Reading of the signal from the sensor(s) can be carried out both in the form of position, speed and acceleration. The method of reading will be dependent on the type of sensor selected. As an example, a magnetic sensor element is easily read with a magnetometer. A signal from an accelerometer is normally read as an electrical signal registered through wires connected to the sensor.

When reading a signal from an accelerometer, the voltage is read as a function of acceleration. A Fourier transform of this signal will be the preferred procedure used to monitor changes in the signal. A further description of the method of doing this is given in the examples below.

Example 1

Experiments have been carried out with two biaxial accelerometers (ADXL-202 carried by Analogue Devices in Norwood, MA, USA) mounted at 90° with respect to each other in order to form a triaxial collection of acceleration data. These sensors can give digital or analogue output signals that are proportional to the acceleration. In the experiment, sampling at a higher rate (1 kHz) was provided by use of the analogue output from the sensors. An operational amplifier was used for buffering the signals in order to render them more resistant to ambient noise, in particular to 50 Hz from the mains. The electronics and two accelerometers were placed in a small polymer box and sealed. Small holes were made in the base plate, which holes were used for attaching to the heart (sewing). The signals were processed as described below.

The above sensor was fastened with four sutures to the myocardium of the apex of a pig's heart. After a short period (5 min.) arterial pressure was applied centrally to the left anterior descending cardiac artery. Occlusion of the LAD (Left Anterior Descending) (after approx. 4 min) to create ischemia. After approximately 6 minutes, the heart is ischemic and fibrillating.

In principle, the speed and position of the sensor may be reconstructed by a single and double integration of the acceleration signal. However, this is not entirely correct, as the rolling of the sensor is not measured, but the main problem is the presence of noise, as integration of noise results in Brownian motion. This may conceivably be solved either by filtering out as much integration noise as possible or by constructing a parameterized model of the heart's acceleration, which is then fitted to the measurement data. Such a model may for instance be based on a truncated Fourier series. However, in order to detect only abnormal heart activity, it would be more advantageous to base further analyses directly on the acceleration signal. Such analysis is described in greater detail in the following.

The accelerometer is sampled at regular intervals. Each sample consists of three components, the acceleration in the x, y and z directions (relative to a system of coordinates linked to the actual accelerometer). If i denotes the time interval (i = 1, 2,....) this gives three time sequences, called e.g. x_i, y_i and z_i. Due to the weight, these time sequences will include a considerable offset, that is the average will not be 0 over time. As this component of the acceleration has no connection with the heart activity, this is undesirable. Therefore, a sliding average is removed from each time sequence, giving new time sequences u_i, v_i and w_i. To be more precise,

$$u_i = \frac{1}{n+1}\sum_{k=0}^{n} x_{i-k}$$

and correspondingly for

$$v_i = \frac{1}{n+1}\sum_{k=0}^{n} y_{i-k}$$

$$W_i = \frac{1}{n+1} \sum_{k=0}^{n} Z_{i-k}$$

Here n indicates the length of the window, which should be great enough to allow the heart to beat several times in the course of n samples.

Now a_i denotes the length of the vector with components u_i, v_i og w_i. This quantity will then measure the acceleration of the heart wall without taking into account the direction of the acceleration. The direction of the acceleration was expected to be approximately constant and normal to the heart wall, so that no information was lost through studying only the length (if a suitable sign is defined for a_i). This was found not to be the case; on the contrary, the direction of the acceleration varied in almost all directions. In the following, the analysis is nevertheless limited to the time sequence a_i, as a one dimensional time sequence is easier to process, and it turns out that enough information has been kept to allow abnormal heart activity to be detected at an early stage.

As an example, Figures 2a and 2b show the acceleration a_i before and after occlusion in the previously mentioned experiment. One can see differences in the signal, but the nature of the change is difficult to establish without further signal processing.

The analysis of a_i is based on a fast Fourier transform (FFT) that estimates the frequency distribution of a signal. Therefore the acceleration is sampled a certain number of times, for instance k times, to give a finite time sequence $a_1,........., a_k$. Then FFT is applied to this sequence so as to give a new sequence X_i. Each element X_i measures the energy of a frequency f_i in the time sequence a_i. If T denotes the time between each sample, we find that $f_i = \frac{i}{2T}$

When studying the frequency image X_i one will find big peaks at the frequency that corresponds to the pulse rate of the heart, and also the first multiples of this. Then if F denotes the pulse, frequency peaks will be found at the following frequencies: F, 2F,

3F,.... The X_i that correspond to different frequencies from these are approximately 0.
In further analysis therefore, it is sufficient to consider the X_i that correspond to these
frequencies. So A_1 denotes the X_i that corresponds to the pulse F, A_2 denotes the X_i
that corresponds to 2F etc. It is enough to look at a relatively small number of A_i, for

5   instance the first 10 (A_i approaches 0 when i increases). It has been observed that the
numbers A_i remain approximately constant for a healthy heart. If the heart is disturbed,
the A_i's change but return to the original pattern when normal heart activity is resumed.
In experiments in which the LAD was blocked, a marked change could be observed in
the A_i's after a short time, long before fibrillation occurred. Based on this, we envisage

10   that one set of A_i can be determined, which applies to a normal, healthy heart, and then
a subsequent sequence A'_i can be compared with this standard, e.g. by calculating the
sum of squares of the differences $A_i - A'_i$. This yields a single number that measures the
deviation from normal activity.

15   An interesting question is whether there is a universal set of A_i for a healthy heart or
whether this is sensitive to the positioning of the accelerometer, whether there will be
individual differences etc. New experiments will be able to determine this.

As an illustration of the above described principle, reference is made to Figure 3, which

20   shows the development with time of the frequency distribution of the signal a_i, in the
form of a spectrogram. Each vertical line is an approximation of the frequency
distribution at a given point in time. In order to clarify the spectrogram, it may be
shown in colours with the frequency distribution indicated e.g. on a scale of colour from
blue via yellow to red as the strongest. The harmonies of the pulse A_1, A_2, ... will then

25   appear as horizontal yellow lines. Upon occlusion, which takes place about 530-570
seconds after the start of the experiment, the intensity of the harmonies can be seen to
change. This is shown more clearly in Figures 4a-c, which show the frequency
distribution around the times 200, 450 and 650 seconds. Thus the first two are from
before the occlusion and are almost identical. Figure 4c on the other hand, is from after

30   the occlusion, and shows a marked deviation from the other two. Furthermore, Figure 5
shows, as an example, the energy X_i that corresponds to the fourth harmony A_i of the

pulse for a specific frequency (approx. 5 Hz) in Fig. 3 with time, the energy peak of the curve corresponding to red in the above mentioned scale of colours.

The diffuse band around 300 seconds is caused by the surgeon fastening the sutures in
5   order to prepare for occlusion. It is worth noting that Figures 4a and 4b show the frequency distribution to be unaltered by this disturbance. This strengthens the hypothesis that a change in the frequency distribution indicates abnormal heart activity. During the experiment, occlusion sutures were placed in the myocardium around LAD (Left Anterior Descending) at 300-450 seconds after the initiation of the experiment, in
10   order to prepare for occlusion. At 530-570 seconds, LAD is fully occluded, and the logging of the acceleration continues until the heart fibrillates. Figure 3 shows this to take place around 700 seconds after the start of the experiment, where the heartbeat at 1.7 Hz decreases (weaker curve). The first 150 seconds also show a blurred curve, which in all likelihood is caused by the heart becoming stressed during the fastening of
15   the sensor.

The frequency distribution then provides an opportunity of detecting a difference in the acceleration before and after occlusion. The strength of the heartbeats that are harmonic to 1.7 Hz is altered after the occlusion. For instance, the fourth harmonic at 6-7 Hz is
20   much stronger after the occlusion, while the sixth harmonic at approximately 10 Hz is weaker. This situation is shown more clearly in Figures 4a-c, which show the energy calculated by means of fast Fourier transform (FFT). Fig. 4a shows the calculations for the intervals of 200-210 seconds, Fig. 4b for the intervals of 450-460 seconds and Fig. 4c for the intervals of 650-660 seconds. It should be noted that Fig. 4a and Fig.4b are
25   almost identical and similar to other intervals taken before the occlusion, as long as these are not within the disturbed area within which the implantation of the sensor takes place. After occlusion however, the image changes completely, cf. Fig.4c. As mentioned, Fig. 4c is shown for the interval 650-660 seconds, but the other intervals after the occlusion will display similar curves, though not as consistently identical as
30   before the occlusion.

Changes in the frequency distribution can then be seen as a measurement of imminent ischemia, and this change can trigger an alarm for taking the required measures. I.e. when the frequency distribution dips below a predetermined value, the alarm is triggered. This value may be set e.g. with respect to the frequency distribution measured immediately after the insertion of the pacemaker with the accelerometer.

In conclusion, a summary of the above described analysis:

1. Sample the accelerometer a number of times, remove offset by means of a sliding average and calculate the length a_i of the acceleration vector.

2. Calculate the frequency distribution of the time sequence a_i by means of FFT.

3. Based on the frequency distribution found, determine the pulse and let A_1, A_2,...be the energy of the first multiples of the pulse frequency.

4. Compare the set A_i with a standard set for a healthy heart by calculating the sum of squares of the differences between A_i and the standard set. A large sum of squares indicates abnormal heart activity.

Example 2

The object of this investigation was to detect the movement of the surface of the heart by means of a piezoelectric accelerometer for early warning in the case of ischemia during coronary surgery. The normal procedure for coronary bypass surgery was followed, CABG (Coronary Artery Bypass Grafting), LIMA-LAD with an open sternum. The accelerometer was fastened to the apex (left ventricle) for accelerometer measurements on occlusion of the LIMA and LAD respectively, in order to measure the changes in movement during ischemia (poor supply of blood to the heart muscle).

- Upon occlusion of the LAD the result of the anastomosis could be tested by looking at changes in the pattern of movements.

- Upon coincident occlusion of the LIMA the changes in movement during ischemia could be tested.

The details of what was to be investigated were as follows:

- How early can one detect ischemia by means of changes in the pattern of movements on 100% occlusion of the LAD, measured by means of accelerometers and analysed by means of fast Fourier transform (FFT) with continuous calculation of changes in the frequency spectra.?

5   - How sensitive is this detection to the placement of the sensor?
- How sensitive is the detection to the axial direction being measured?
     - Resultant of the x, y, z direction
     - One axis only
- What is the specificity of the system?

10   - What is the sensitivity of the system?

The accelerometer described in example 1 was fastened to the apex (left ventricle) of a pig where LIMA had been grafted to LAD through surgical intervention. LIMA and . LAD were closed, and the effect on the signal from the accelerometer was detected in

15   order to measure the changes in movement during ischemia (poor supply of blood to the heart) as described below. Upon occlusion of the LAD the functionality of the anastomosis will be tested by looking at changes in the pattern of movements. Upon coincident occlusion of the LIMA the changes in movement during ischemia will be tested.

20

The following was the procedure for logging of data:
1. The accelerometer was glued to the apex.
2. Measurements with installed accelerometer started after: a seconds.
3. LAD occluded to induce an ischemic condition after: b seconds.

25   4. Occlusion released to let heart recover, after: c seconds.
5. Logging of accelerometer data stopped.

Measuring : The acceleration along three orthogonal axes hereinafter termed the x, y and z directions, was measured using a newly developed 3D accelerometer. Analogue

30   measurements were logged at 250 samples/s via Labview with DAQ 1200 Data Acquisition Card.

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The log files are listed in table 1 below.

Below there follows a procedure for signal analysis of log data from log for animal testing 1:

5   A 512 point fast Fourier transform (FFT) is used to analyse the raw data, illustrated in Figure 6, which shows unprocessed acceleration data in the x direction:

- Read acceleration measurement from the log file.
- Input the column, i.e. the axial direction, for which analysis was required, as a vector with a length equal to the log length.
10   - Took a 512 point subvector out of this (sample).
- Subtracted dc offset from the vector elements.
- Performed an FFT analysis with a 512 sample width, which resulted in a new vector but with complex elements.
- Calculated the "effect spectrum" by multiplying the FFT vector by its conjugate and
15   then dividing by the length of the vectors. This provides a measure of energy as a function of frequency in the signal.
- Stored the first energy vector (see Figure 7). This vector can form a reference effect spectrum for the subsequent calculations.
- Then calculated the same energy vector with a floating window at increments that
20   were a balance between the calculating speed and the requirement for accuracy/sensitivity, see Figures 8a and 8b, which show the energy spectrum after 60 and 100 seconds, respectively.
- The Euclidean distance between each of the new vectors and the first energy vector was calculated through the square root of the energies of each x value squared.
25   - Alarm as an indication of ischemia is triggered when :
  - The upper limit of the Euclidean distance (higher than the highest normal value found empirically) is exceeded.
  - The derivative of the same Euclidean distance exceeds a found upper limit.
- Euclidean distance is plotted in real time, to allow a trained operator to see abnormal
30   changes also from a graphical image. Figure 9 shows the development of the Euclidean distance from a floating effect spectrum to a reference spectrum (see Fig. 6), i.e. at the beginning of the measurements with the data from the floating

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window, so as to make it possible to see a change in the signal with respect to the first sampling, which then acts as a reference. Figure 9 clearly shows an increase in this differential value in the range 80 to 170 seconds

5   Figure 9 also shows the differential value for the spectrum along a first axis, called the x axis. In the test, the measurements were carried out using an accelerometer that is sensitive to movement along three axes, and Figures 10a and 10b show corresponding measurements performed along the y and z axes along the same time axis as for Figure 9.

10

Figure 11 shows a signal difference between the last measured spectrum and the previous, so as to allow changes in the signal to be registered. As is apparent from comparison with Figure 9, the analysis method of Figure 11 provides a strong signal at the same points as those that show an increase in signal in Figure 9.

15

The experiments were carried out with two prototypes, where the signal processing of the signal from the first prototype was implemented into MatLab in the following way:

```
load pig250Hz_150802_apex1_80_85sec_35_lad.TXT;
x=pig250Hz_150802_apex1_80_85sec_35_lad(:,2);

x_window=x(1:512);
x_dc=x_window-mean(x_window);
fftx=fft(x_dc,512);
Pxx1 = fftx.* conj(fftx) / 512;
for i=2:50:(length(x)-512)
    x_window=x(i:511+i);
    x_dc=x_window-mean(x_window);
    fftx=fft(x_dc,512);
    Pxx = fftx.* conj(fftx) / 512;
    dist_eucl_x(i)=sqrt(sum((Pxx-Pxx1).*(Pxx-Pxx1)));
    i
```

```
end
figure
plot(dist_eucl_x);
```

5   Figure 12 shows a result similar to that of Figure 9 for another experiment with another
prototype, where the signal processing from the second prototype is implemented into
MatLab in the following way :

```
load pig250Hz_150802_apex1_80_85sec_35_lad.TXT;
x=pig250Hz_150802_apex1_80_85sec_35_lad(:,2);
```

10

```
x_window=x(1:512);
x_dc=x_window-mean(x_window);
fftx=fft(x_dc,512);
Pxx_old = fftx.* conj(fftx) / 512;
for i=2:50:(length(x)-512)
    x_window=x(i:511+i);
    x_dc=x_window-mean(x_window);
    fftx=fft(x_dc,512);
    Pxx_new = fftx.* conj(fftx) / 512;
    dist_eucl_x(i)=sqrt(sum((Pxx_new-Pxx_old).*(Pxx_new-Pxx_old)));
    Pxx_old = Pxx_new;
    i
end
figure
plot(dist_eucl_x);
```

As can be seen, the experiments show a surprisingly good correlation between the flow
of blood in LAD (supply of blood to the left ventricle - apex) and changes in the
accelerometer measurements. Proof of ischemia in apex can thereby be detected very

30   early on, by accelerometer measurements being analysed in real time by means of fast
Fourier transform (FFT) and calculations of Euclidean distance between the FFT spectra
and the first FFT spectrum. A marked change in the Euclidean distance was detected

16

almost immediately upon occlusion and opening respectively, of the LAD. (See Figure 9 under "Animal testing 1", Acc X-direction, occlusion at 80 sec., reopened at 160 sec..

5   Figures 13-16 show the motion sensor in use on a heart that has been through a so-called bypass operation. As can be seen, the sensor is attached to a selected position on the surface of an active heart for registration of the movements of the heart in this position. According to a preferred embodiment of the invention, more, e.g. 2 or 3, sensors may be attached in different places on the heart. In this manner, post-operative monitoring of the heart after bypass surgery can be achieved. In order to achieve this,

10   the motion sensor preferably has dimensions and fasteners designed to be removed from the position without requiring surgical intervention, e.g. dimensions such as those of a temporary pacemaker electrode.

In the figures, a bypass is carried out past an area of reduced blood flow by

15   reconnecting blood vessels 14 in order to supply blood to a specific area, and the sensor 2 is placed in an area where changes in the movements of the muscle caused by lack of blood supply, can be detected. As is apparent from Figure 14, the sensor is preferably sensitive in three directions.

20   Figure 15 shows an example of a circuit diagram for the above acceleration sensor ADXL-202 used according to a preferred embodiment of the invention.

Figure 16 shows a sensor that is placed on the heart to carry out the measurements and is connected to a data acquisition unit 10, a unit 11 for signal processing 11 and further

25   to a device 12 that displays the processed data on a screen and/or gives an acoustic warning in the case of deviations. The changes displayed or predicted can then form the basis 13 for deciding whether further surgical treatment is required or the patient can be pronounced fit.

30   Preferably, the position selected is a central point in that part of the heart muscle which after the operation is supplied with blood from the revascularised coronary artery.

17

Preferably, the motion sensor comprises an accelerometer that is sensitive to acceleration in at least one direction, but may as an alternative or supplement also comprise a gyroscope for measuring rotary movement in the locating point of the sensor. The gyroscope will be able to register other types of changes, e.g. if the selected

5   position itself is at rest but the adjacent points are moving, causing twisting in that position.

The registered movement is transmitted to a calculation unit located externally of the patient, e.g. for Fourier analysis of the raw data from the sensor.

10

Preferably, the motion sensor according to the invention for registration of the movements of a heart will have a sensitivity of at least 600mV/g within a frequency range of 200Hz (band width) with a maximum amplitude of 2.5V. In order to allow it to be used in post-operative applications, its dimensions should be smaller than

15   1.5x1.5x4 mm, preferably of the order of 1x1x2mm, and it should be provided with an outer material that does not cause reactions in biological materials, and devices for attaching it to a selected position on the surface of the heart, which sensor moreover comprises a signal conductor for transferring registered information to a calculation unit externally of the patient.

20

As mentioned, the motion sensor will preferably comprise an accelerometer having at least one direction of sensitivity; an accelerometer having three directions of sensitivity will be advantageous in order to register the direction of the movements.

25   The invention further comprises a system for monitoring changes in the movements of a heart muscle, such as shown in Figure 17, where the sensor is designed to emit signals that reflect the functioning of the heart, to a calculation unit. It may be tied in to further biosensors that are integrated into the accelerometer or fixed to the pacemaker electrode in order to give off signals that are characteristic to the functions of a heart.

30

The system further includes an amplifier and a calculation unit designed to amplify and calculate the signals, and a device for indicating the deviation upon comparison, e.g. by

18

use of fast Fourier transform to determine the frequency distribution. The calculation

unit determines the frequency distribution of the signals and compares this with a preset

standard distribution, e.g. the first distribution measured immediately after the insertion

of the sensor, such as in example 2 above. The system may further comprise a device

5   for indicating the deviation from the predetermined values, which comprises an alarm

transmitter designed to emit an alarm signal when the deviation from said standard

distribution exceeds a certain level.

Table 1. Logging during two different animal tests:

10

File name :	logging – base line [s]	occlusion [s]	reopening [s]	Comments (The times are relative)
pig_150802_apex1_80_85sec_35_lad.TXT	80	85	35	Log for 80s before occlusion for 85s before reopened for 35s (total log 200s)
pig_200802_apex1_30sec_128sek_60sec_lad.TXT	30	128	60	Log for 30s before occlusion for 128s before reopened for 60s (total log 218s)

C l a i m s

1.   Use of a motion sensor where the sensor is fastened to a selected position
on the surface of an active heart for registering the movements of the heart in this
position.

2.   Use in accordance with Claim 1, c h a r a c t e r i s e d   i n that the use
takes place post-operatively in connection with a bypass operation.

3..   Use in accordance with Claim 1, c h a r a c t e r i s e d   i n that the
position is selected as a central point of that part of the heart muscle which after an
operation receives blood from the revascularised coronary artery.

4.   Use in accordance with Claim 1, c h a r a c t e r i s e d   i n that the
motion sensor is designed by means of its dimensions and fastening devices to be
removable from the position without requiring surgical intervention.

5.   Use in accordance with Claim 1, c h a r a c t e r i s e d   i n that the
motion sensor comprises an accelerometer that is sensitive to acceleration in at least one
direction.

6.   Use in accordance with Claim 1, c h a r a c t e r i s e d   i n that the
motion sensor comprises a gyroscope for measuring rotary movement at the point of
attachment of the sensor.

7.   Use in accordance with Claim 1, c h a r a c t e r i s e d   i n that the
registered movement is transmitted to a calculation unit located externally of the patient.

8.   Use in accordance with Claim 1, c h a r a c t e r i s e d   i n that the
motion sensor is incorporated into a temporary pacemaker electrode.

20

9.   A motion sensor for registering the movements of a heart, which sensor is a motion sensor with a sensitivity of at least 600mV/g within a frequency range of 200Hz (band width) with a maximum amplitude of 2.5V, has dimensions of less than 1.5x1.5x4mm and is provided with an external material that does not cause reactions in biological material, and devices for fastening to a selected position on the surface of the heart, which sensor furthermore comprises a signal conductor for transmitting registered information to a calculation unit located externally of the patient.

10.   A motion sensor according to Claim 9, c h a r a c t e r i s e d i n that the dimensions of the sensor are less than 1x1x2mm.

11.   A motion sensor according to Claim 9 or 10, c h a r a c t e r i s e d i n that it comprises an accelerometer having at least one direction of sensitivity.

12.   A motion sensor according to Claim 9, 10 or 11, c h a r a c t e r i s e d i n that it comprises a gyroscope for measuring rotary movement about at least one axis at the selected point.

13.   A system for monitoring changes in the movements of a heart muscle, comprising at least one motion sensor according to Claim 9, 10, 11 or 12, where the sensor is designed to be fastened to the surface of a heart and where the sensor is designed to emit signals that reflect the heart activity, to a calculation unit.

14.   A system according to Claim 13, c h a r a c t e r i s e d i n that it further includes biosensors that integrated into the accelerometer or fixed to the pacemaker electrode in order to emit signals that are characteristic to the heart activity.

15.   A system according to Claim 13 or 14, c h a r a c t e r i s e d i n that it further includes an amplifier and a calculation unit designed to amplify and calculate the signals, and a device for indicating deviation upon comparison.

21

16.   A system according to Claim 15, c h a r a c t e r i s e d   i n that the
calculation unit is expected to use fast Fourier transform for determining the frequency
distribution.

5

17.   A system according to Claim 15, c h a r a c t e r i s e d   i n that the
calculation unit determines the frequency distribution of the signals, and that these are
compared with a pre-set standard distribution.

10   18.   A system according to Claim 15, c h a r a c t e r i s e d   i n that the pre-
set standard distribution employed is the frequency distribution calculated immediately
after insertion of the sensor.

19.   A system according to Claim 18, c h a r a c t e r i s e d   i n that it
15   comprises a device for indicating deviation from predetermined values, comprising an
alarm transmitter designed to emit an alarm signal when the deviation from said
standard distribution exceeds a certain level.

20.   A system according to Claim 13, c h a r a c t e r i s e d   i n that the
20   motion sensor is incorporated into a temporary pacemaker electrode.

Fig. 1a

Fig. 1b

Fig. 2a

Fig. 2b
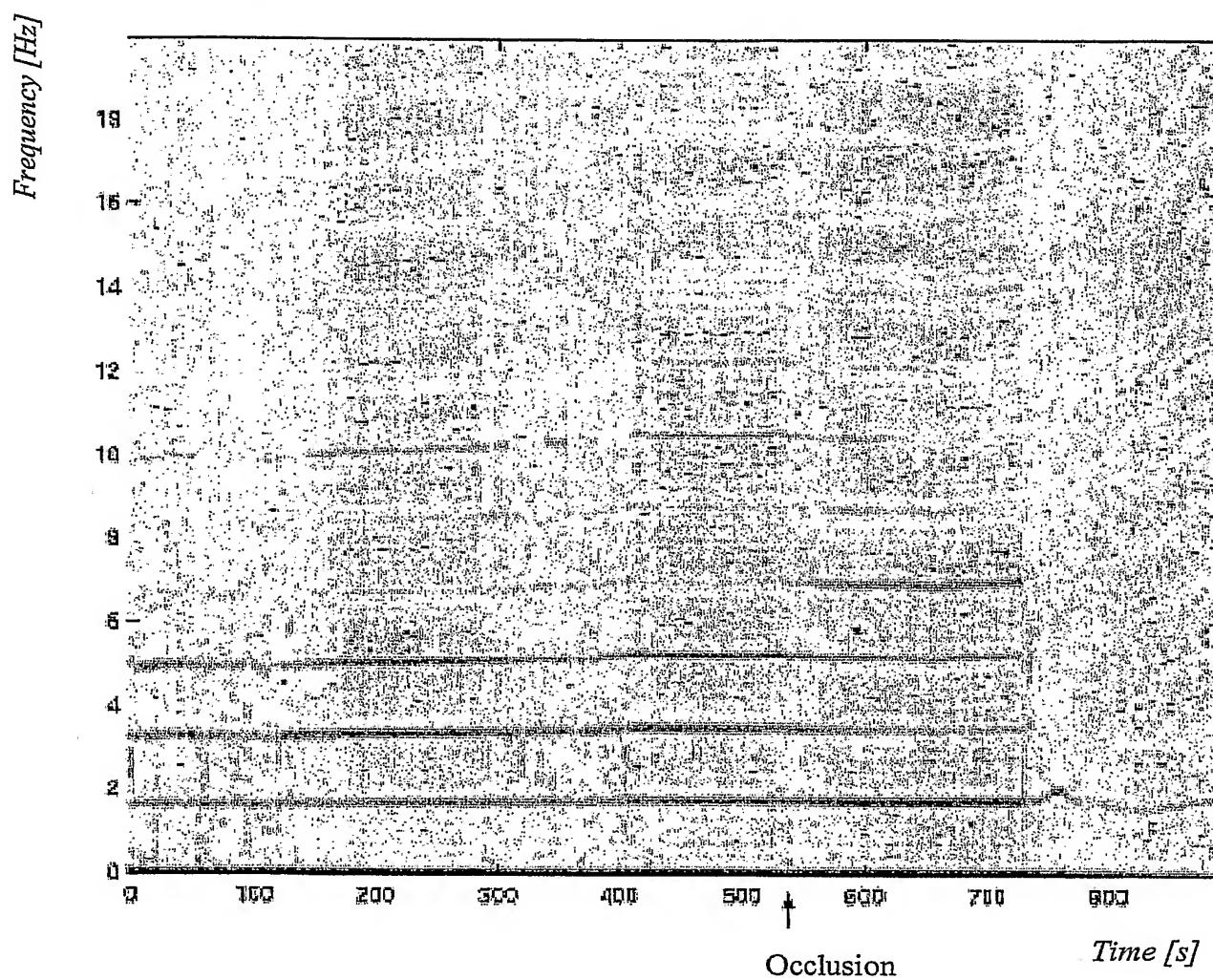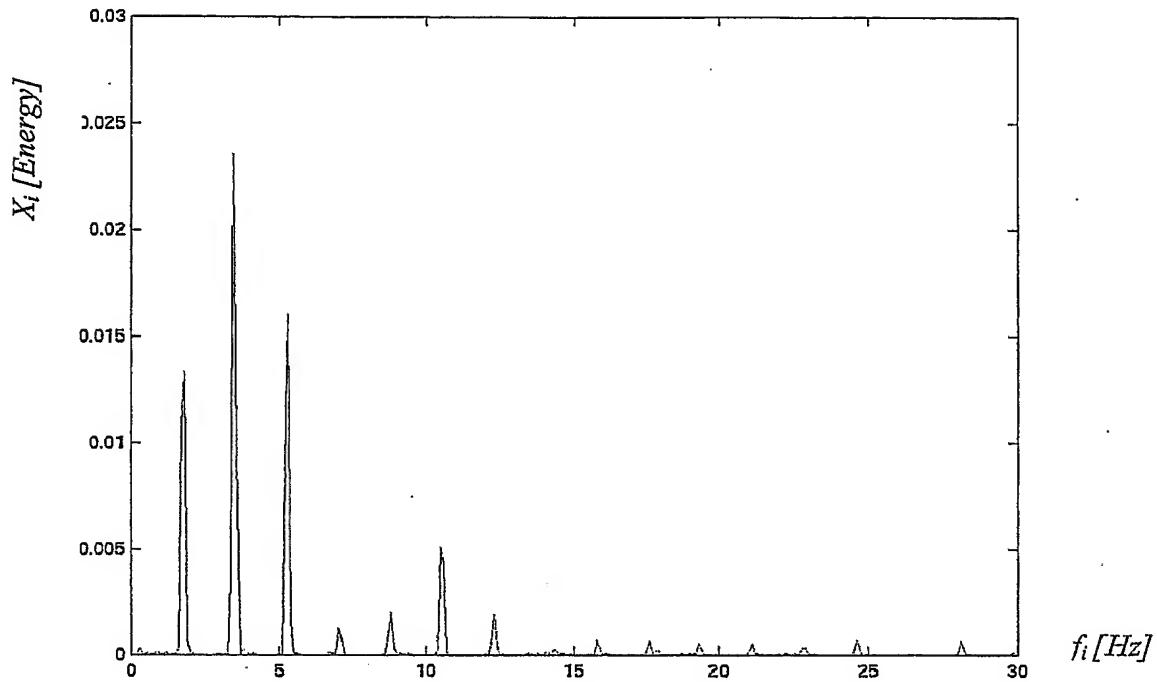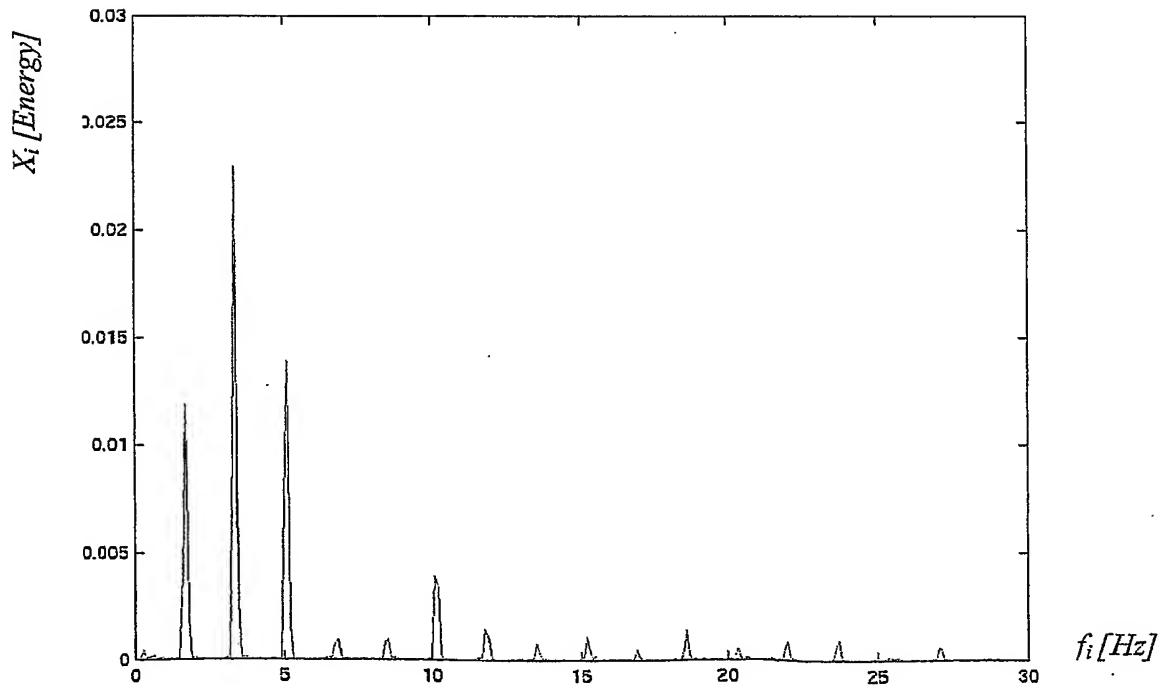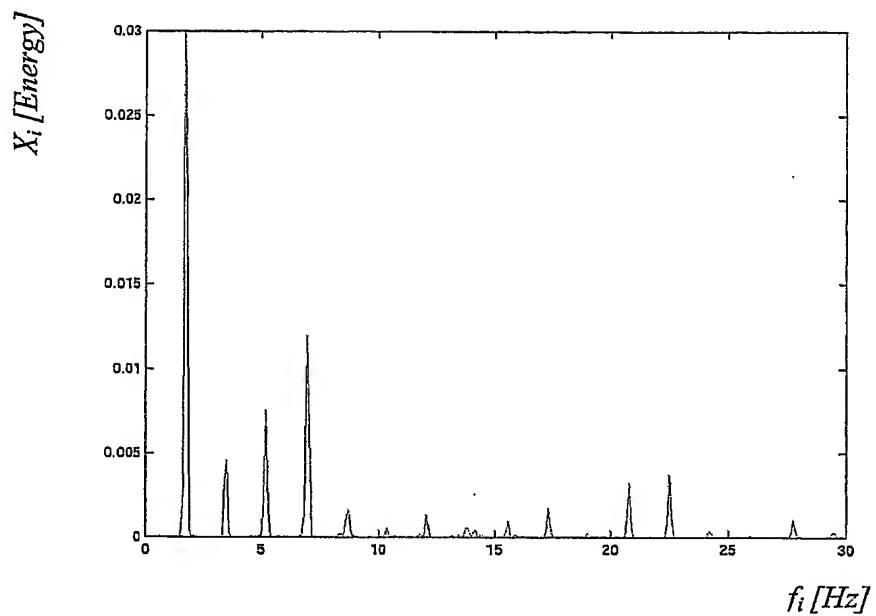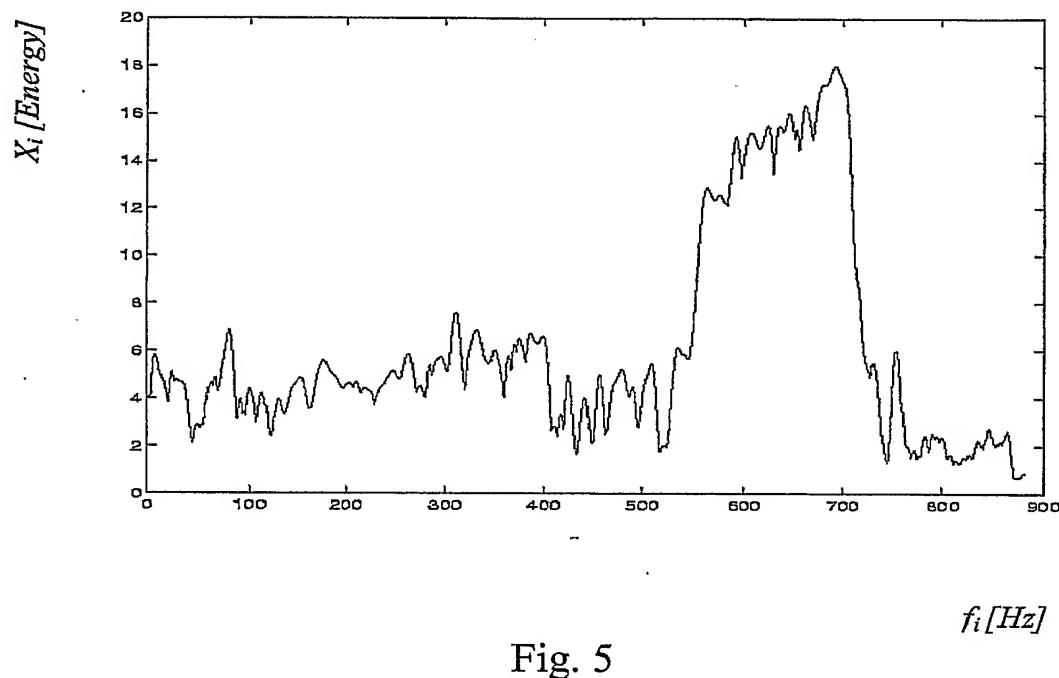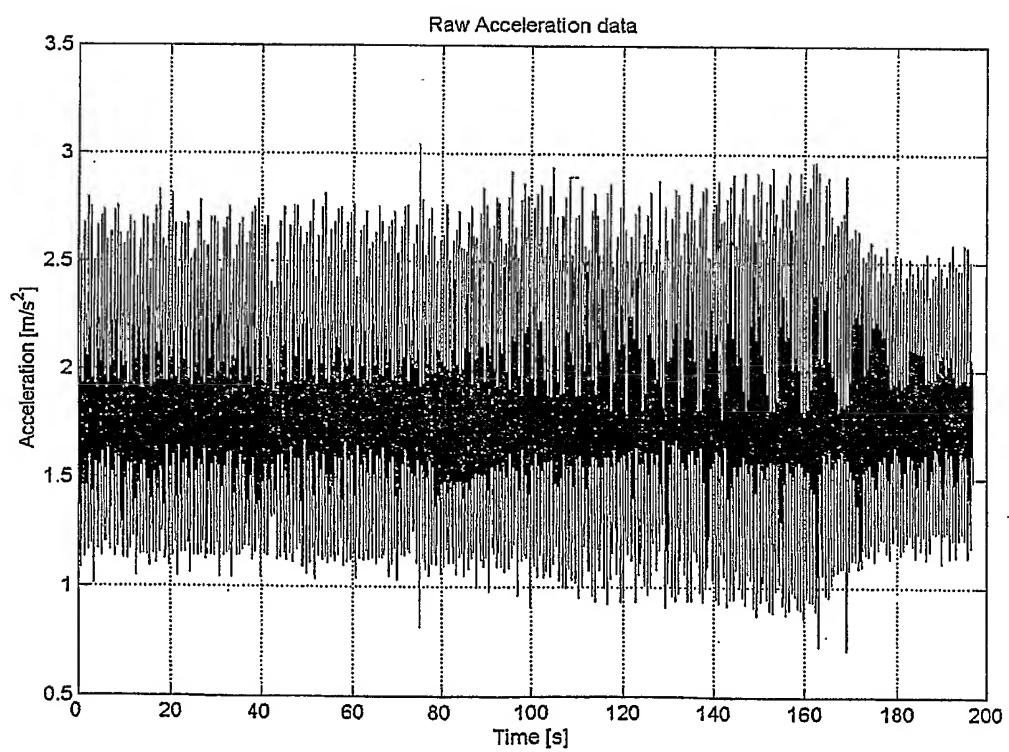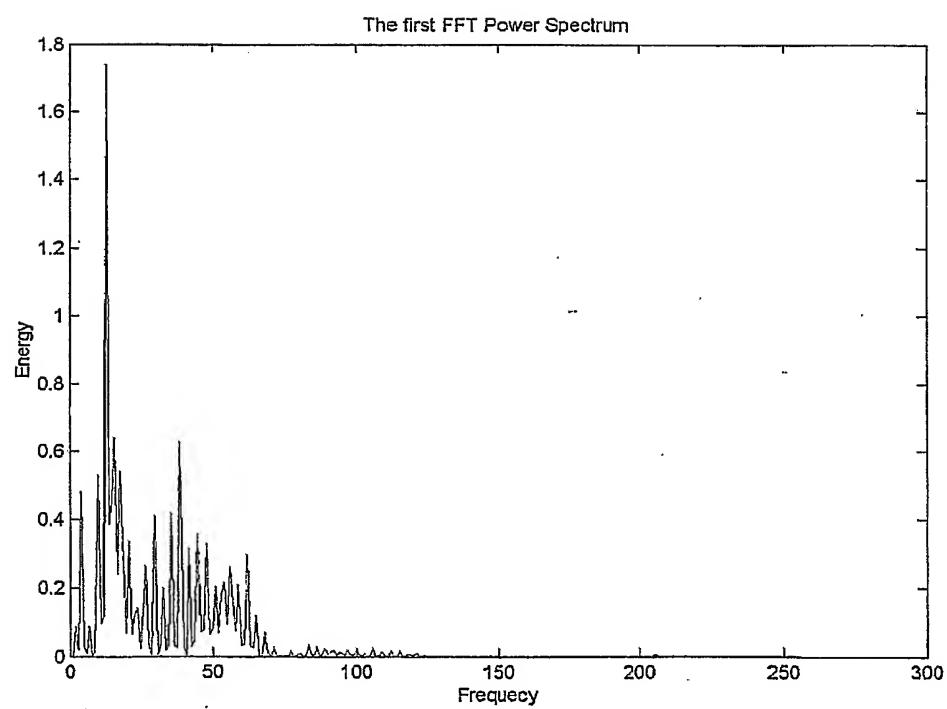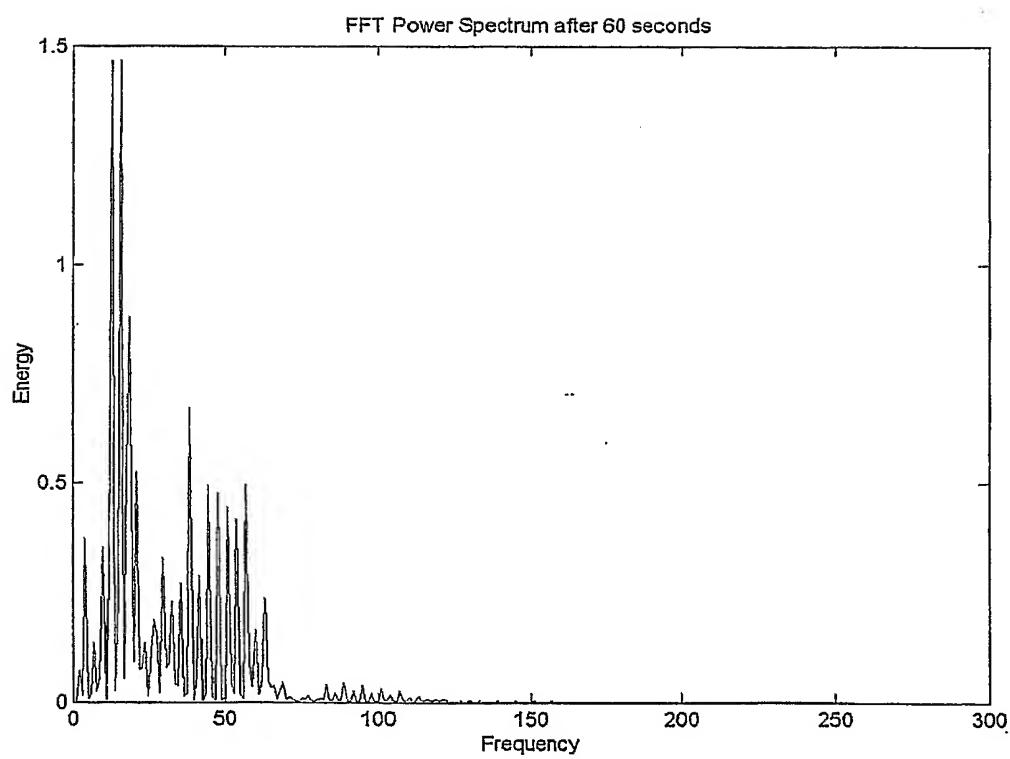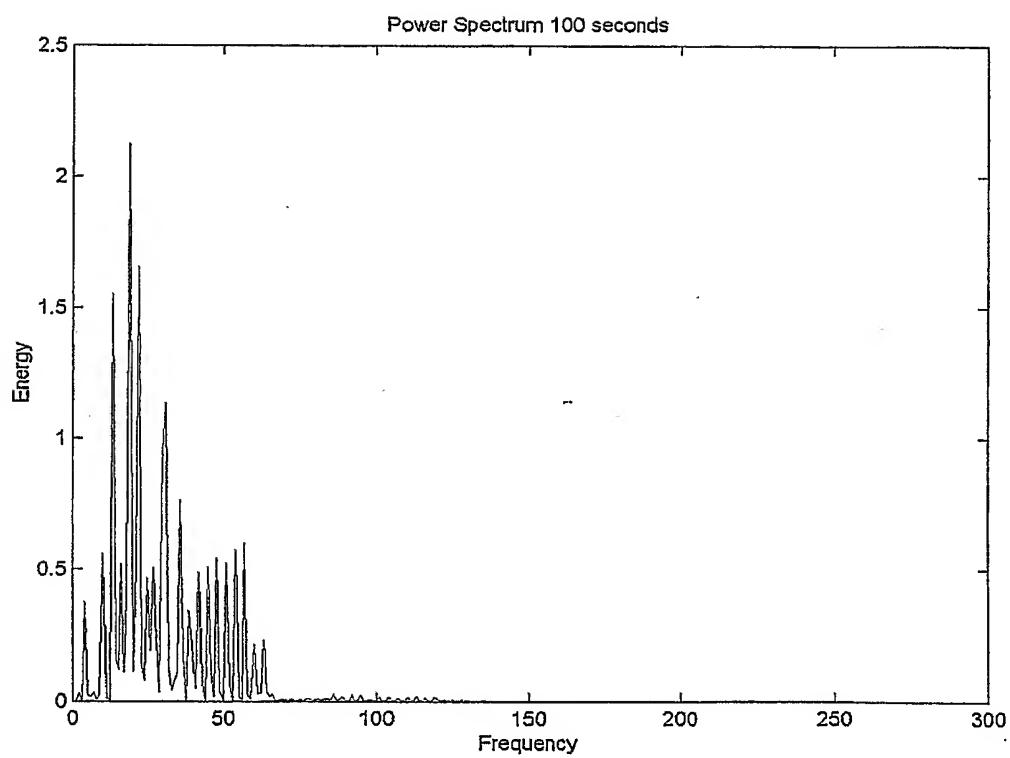
Fig. 3

Fig. 4a

Fig. 4b

Fig. 4 c

Fig. 5

Fig. 6

Fig. 7

Fig. 8a

Fig. 8b

Fig. 9

Fig. 10a

Fig. 10b

Fig. 11

Fig. 12

Fig. 13

LIMA

Bypass 1 : Internal
mammary
artery (IMA) graft
to left anterior
descending (LAD)

Occlusion
of Left Anterior
Descending

LAD

Motion sensor for
three-axis measurement of
heart movements

Fig. 14

ADXL 202 JQC

1358 S (a)

Pin 11/12

22nF

3

X, Y, Z
sensor
signals

10k

3

V_{DD} (5V)

V_{DD}

100µF

10k

18k

Break point for the tripple
x,y,z circuitry

V+ (8V)

1358 S (b)

18k

2,5V

V- (7,7V)

4,7k

COM

Fig. 15

Bypass 1

Decision/
decision
support

Occlusion

Motion sensor

Visualisation
and/or
reporting

Signal
processing

Data
aquisition
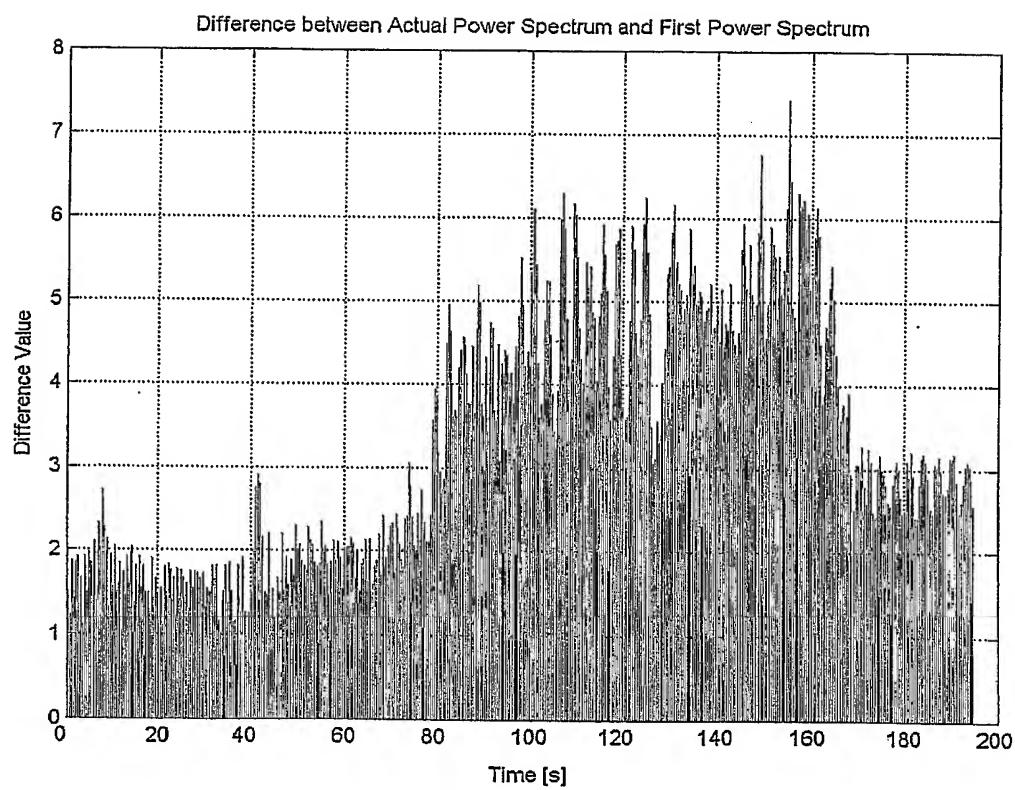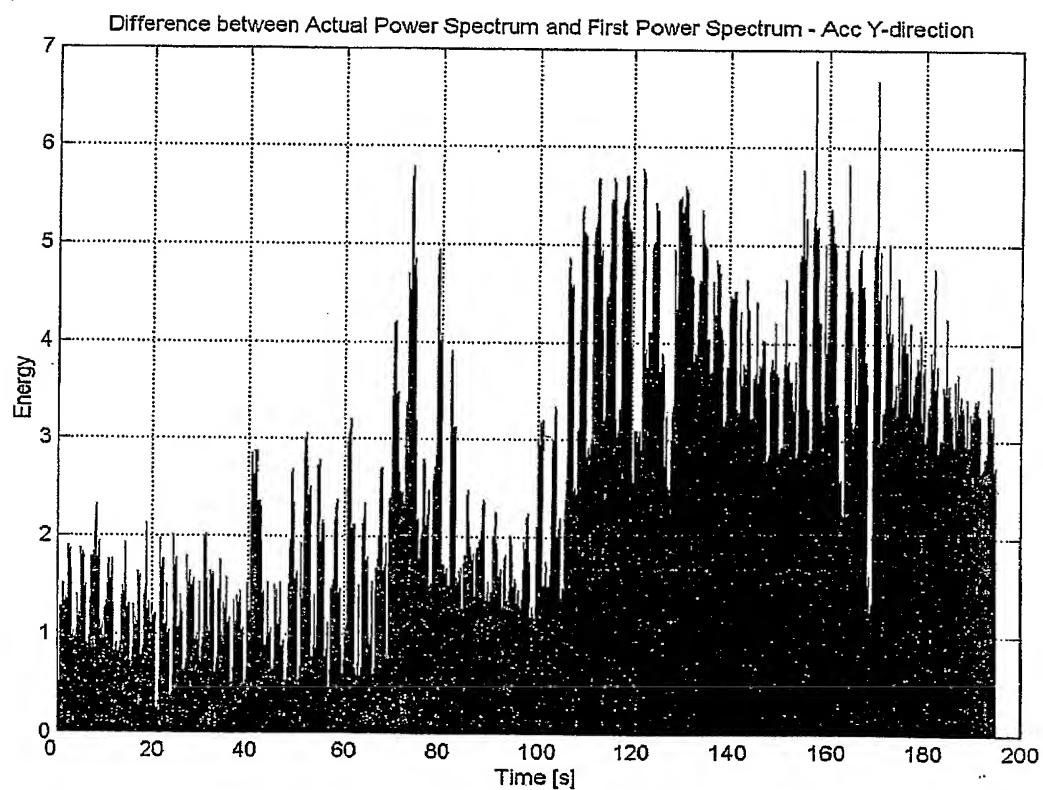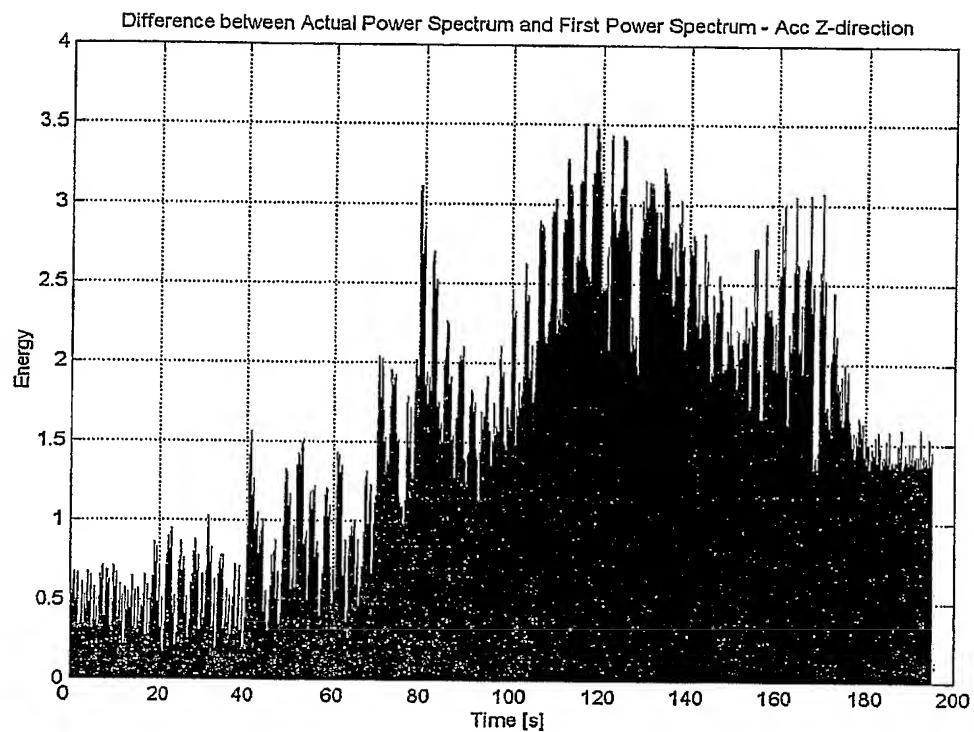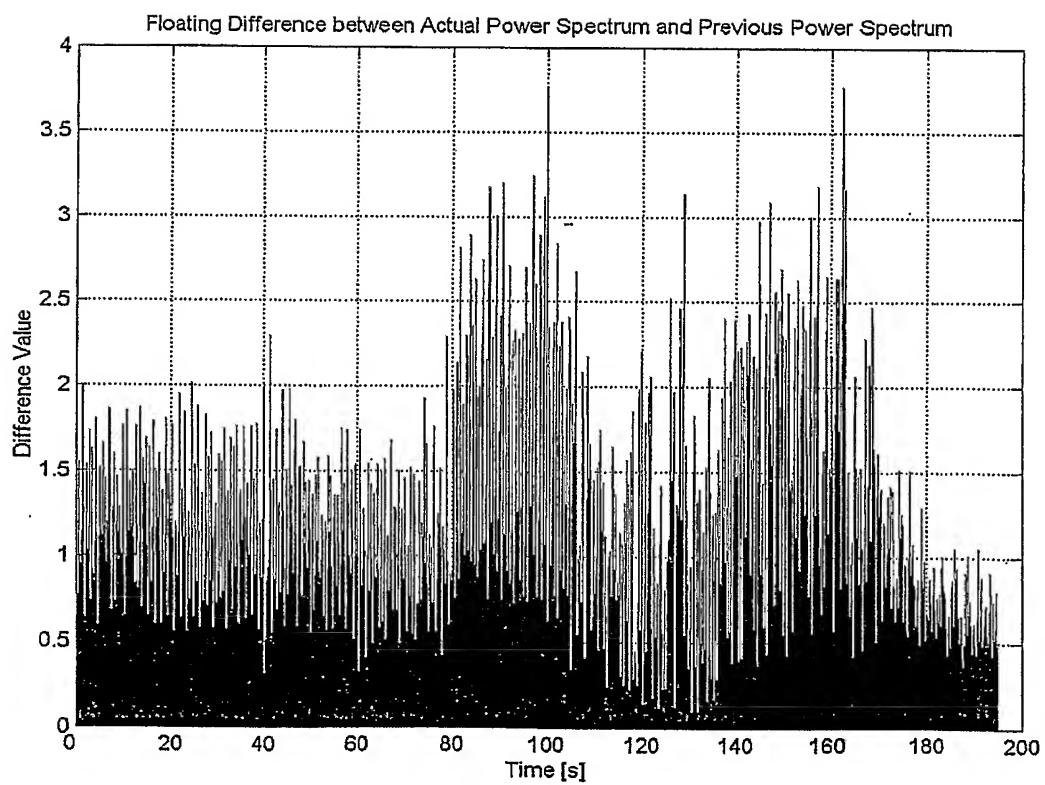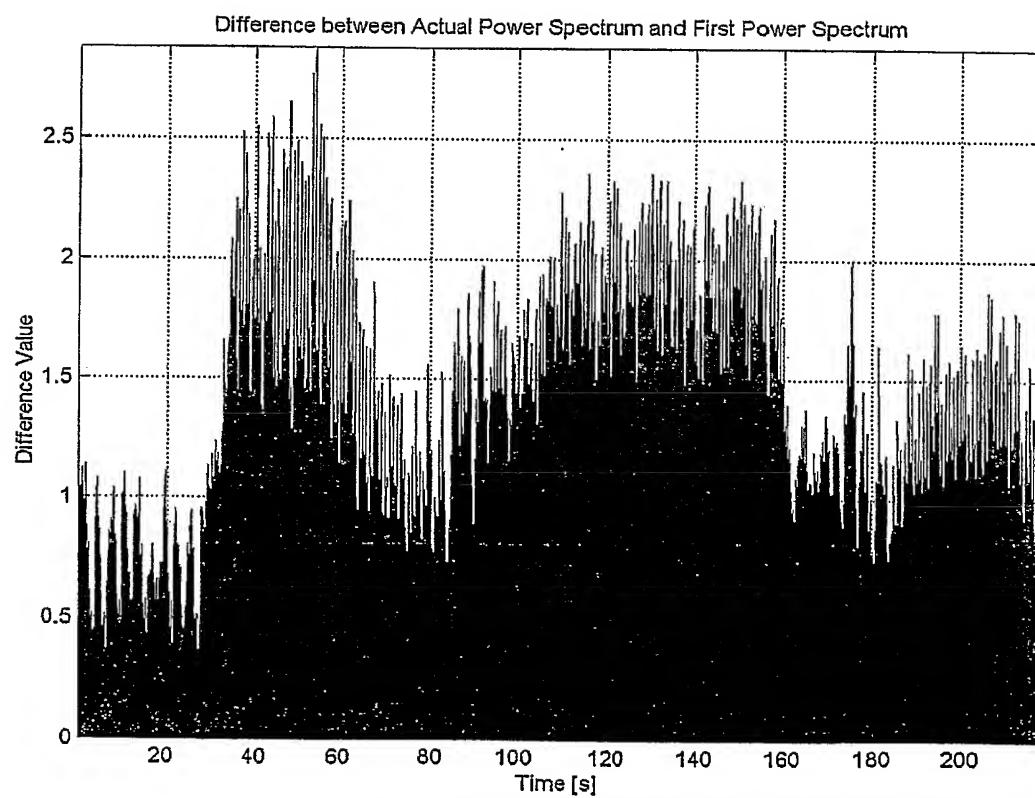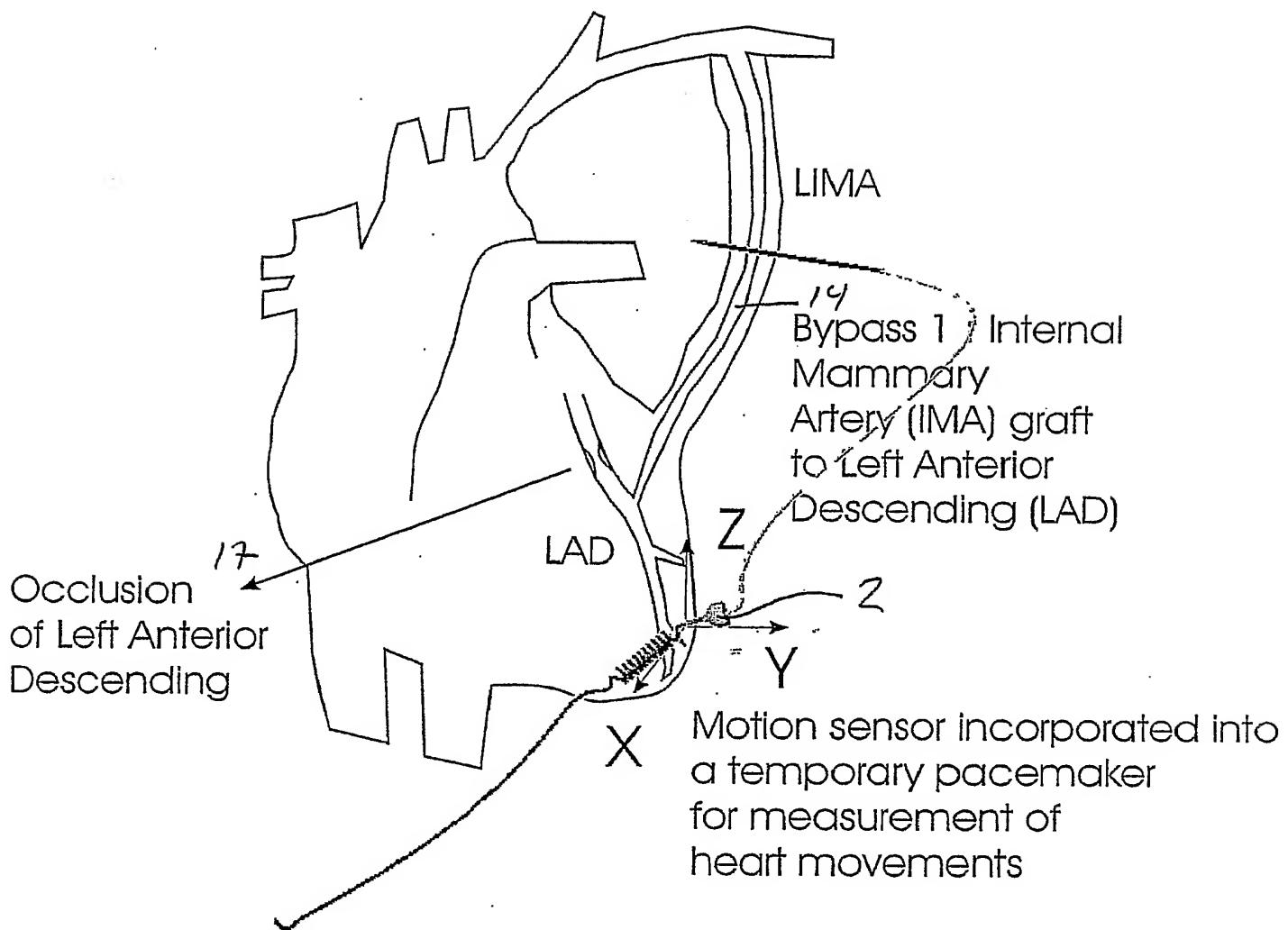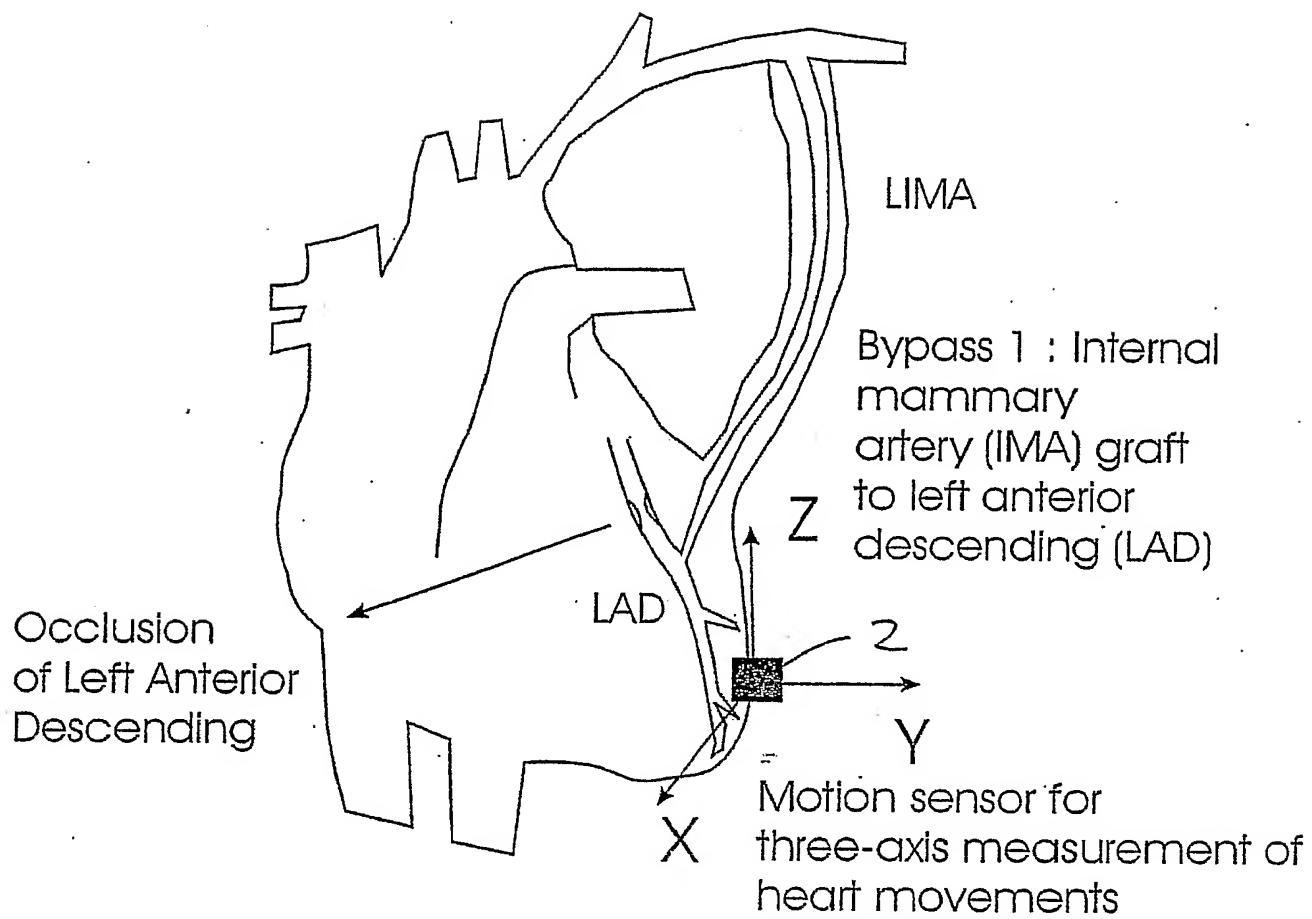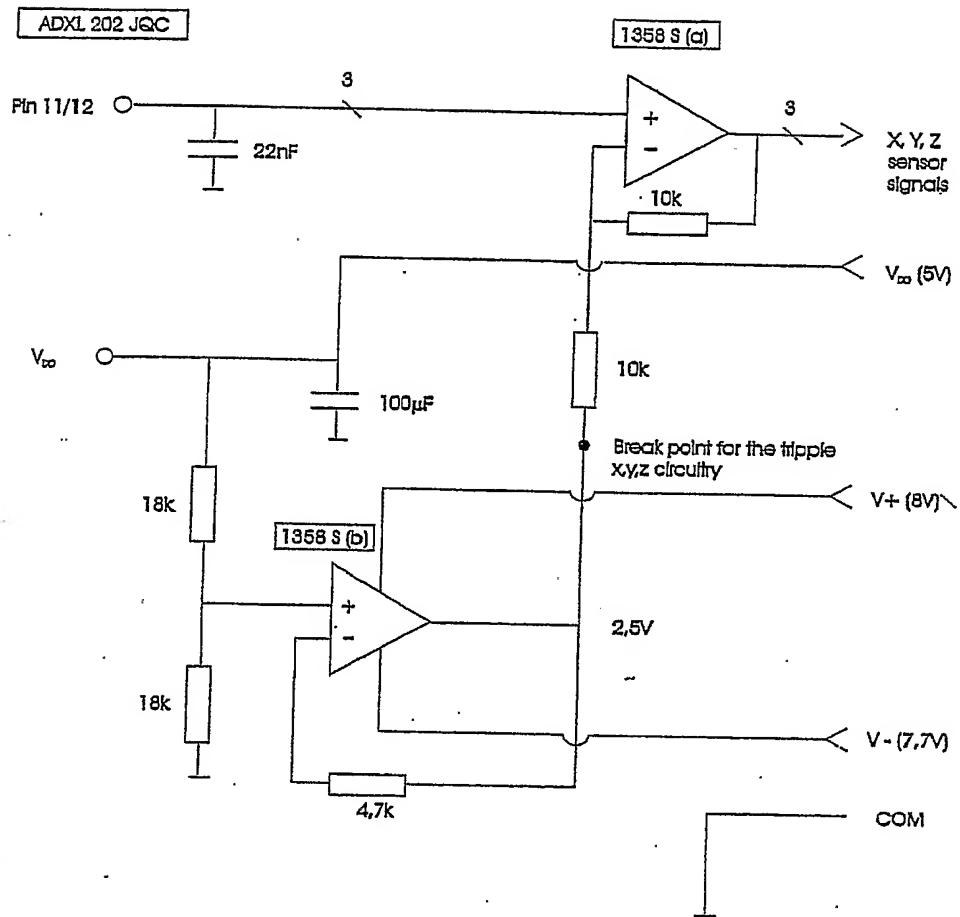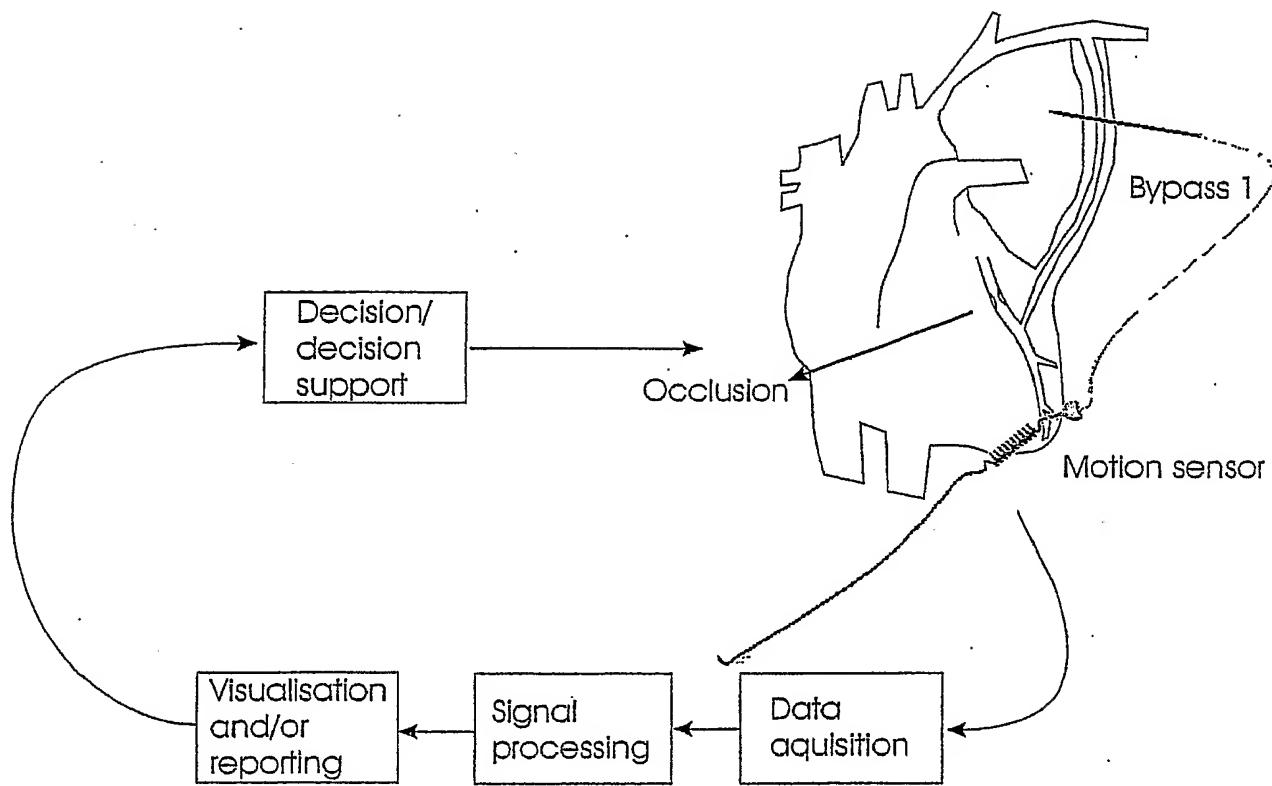
Fig. 16

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/11 // A61B 5/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ, MEDLINE, BIOSIS, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5109842 A (DAVID W. ADINOLFI), 5 May 1992 (05.05.92), column 2, line 2 - line 8	1-20
X	US 5628777 A (SHELDON B. MOBERG ET AL), 13 May 1997 (13.05.97), column 10, line 62 - column 11, line 17	1-20
X	Rickards, A.F. et al "An Implantable Intracardiac Accelerometer for Monitoring Myocardial Contractility" PACE, Vol 19, December 1996, Part I	1-20

| X | Further documents are listed in the continuation of Box C. | X | See patent family annex. |

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 May 2003	0 6 -05- 2003

Name and mailing address of the ISA/	Authorized officer
Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Frida Plym Forsell/mj Telephone No. +46 8 782 25 00

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	IEEE Transactions on biomedical engineering, Volume 39, No 7, July 1992, John C. Wood et al, "Time-Frequency Transforms: A New Approach to First Heart Sound Frequency Dynamics", abstract	1-7,9-19
A		8,20
	--	
X	US 5161540 A (JOHANNES MUELLER), 10 November 1992 (10.11.92), abstract	1-7,9-19
A		8,20
	--	
X	US 4204544 A (CYRIL FELDSTEIN ET AL), 27 May 1980 (27.05.80), column 4, line 4 - line 32	1-7,9-19
	--	

INTERNATIONAL SEARCH REPORT

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-8
   because they relate to subject matter not required to be searched by this Authority, namely:

   see next page

2. ☐ Claims Nos.:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest   ☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July1998)

Claims 1-8 relate to a diagnostic and surgical method practised on the human body. The method is used for monitoring heart state after heart surgery, which is of diagnostic value, and includes a step of implanting a sensor on the surface of the heart, which is a surgical step. Thus, the International Searching Authority is not required to carry out an international search for these claims (PCT Rule 39.1(iv)). Nevertheless, an International Search has been executed for claims 1-8.

Patent document cited in search report			Publication date	Patent family member(s)			Publication date
US	5109842	A	05/05/92	NONE			
US	5628777	A	13/05/97	AU US WO	7331694 5496361 9503086	A A A	20/02/95 05/03/96 02/02/95
US	5161540	A	10/11/92	DE DE EP ES	4029961 59107237 0476242 2084732	C D A,B T	24/10/91 00/00/00 25/03/92 16/05/96
US	4204544	A	27/05/80	NONE			